Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries

Background document

This document provides a summary of the purpose and scope of the fitness check. It is provided for information purposes only and will be replaced by the Fitness Check Roadmap as soon as it is published. It does not reflect a final view of the European Commission and its content may by subject to change.

1. Purpose of the Fitness Check

A Fitness Check ("FC") is a comprehensive evaluation of a policy area that assesses the actual performance of the legislative framework compared to initial expectations and takes a critical look at whether EU activities are fit for purpose and deliver, at minimum cost, the desired changes to European businesses and citizens and contribute to the EU's global role. A Fitness Check pays particular attention to identifying any synergies (e.g. improved performance, simplification, lower costs, reduced burdens) or inefficiencies (e.g. excessive burdens, overlaps, gaps, inconsistencies and/or obsolete measures) within the group of measures and help to identify the cumulative impact of the interventions covered, covering both costs and benefits.

The aim of this particular fitness check is to assess whether the current legislative framework for chemicals is fit for purpose and delivers as intended/expected. It shall:

- assess the overall effectiveness, efficiency, relevance, coherence, and EU added value of this legislative framework, including the procedures to implement the framework;
- identify possible excessive regulatory burdens, overlaps, inconsistencies, obsolete measures and gaps in the legislative framework.

The REACH Regulation is excluded from the scope of this Fitness Check (except for Annex XIII – see under point 4b). It will be covered by another evaluation and another public consultation later this year.

2. Context of the Fitness Check

Chemicals are omnipresent in society, contributing considerably to achieving our high living standard. Chemicals are present in almost every consumer product, in almost every building or construction, and form part of almost every production process, be it food, electronics, toys, clothes or industrial machines. This omnipresence shows how dependent a modern prosperous society is on chemicals but also that the exposure and hence potential human health and environment risks are manifold and multifaceted.

The European Union chemicals acquis has developed over the past 50 years, balancing the need of society to continue to use chemicals and thereby contributing to prosperity, whilst

safeguarding society against the potential human health and environment risks arising from that very use.

The legislative framework for chemicals comprises both chemicals legislation in the strict sense of the word –directly regulating chemical substances and mixtures– and related legislation, e.g. regulating conditions, under which chemicals are manufactured, treated or used (e.g. occupational health and safety or environmental legislation) or regulating products, in which chemicals are used (e.g. some consumer articles, for which certain requirements exist in product-specific legislation).

The development of this framework has been continuous and built on past experiences. Yet there has not been a comprehensive assessment across the European Union chemicals acquis to ascertain if it still meets its primary aims, namely that the European citizen benefits from a high level of protection for humans and the environment and that the EU internal market in chemicals functions well, thereby stimulating innovation and competitiveness. The acquis' relevance and coherence have also not been assessed.

3. Background on the risk management of chemicals

There are several elements of the risk management process for chemicals, typically starting with the identification of hazards of a chemical substance or mixture and ending with risk management measures to control any risks determined by the intrinsic hazards and the exposures related to specific uses or application. The extent to which the steps below are present in the risk management process depends on the specific pieces of legislation.

A hazard is determined by the intrinsic properties of the substance or mixture, i.e. whether its characteristics can lead to health and environmental damages. Hazard identification may occur in both horizontal and sectoral legislation. A key horizontal regulation that mandates the identification of hazards is the CLP Regulation, which upon identification also classifies these hazards as health hazards, physical hazards or environmental hazards.

Depending on the nature and dimension of hazards and the exposure situations involved, risk management measures are taken directly based on the identified hazard classification using generic risk considerations justifying a direct risk management consequence, or based on a specific risk assessment.

Direct mechanisms applying measures to classified substances based on generic risk considerations without further specific assessment of the risk may be justified by specific considerations, such as the characteristics of the hazard, the vulnerability of certain parts of the population (e.g. children), non-controllable or widespread exposure.

A specific risk assessment assesses the probability of occurrence of an adverse effect on man or the environment resulting from a given exposure to a chemical or mixture. The assessment takes into account both the hazards and the potential specific exposures of humans and the environment.

4. Scope of the Fitness Check

a. Topics covered

The FC will consist of the following:

1. Mapping out links between the various hazards identified and the risk management measures taken as a consequence in downstream legislation on the basis of generic risk considerations

This will include an analysis of the hazard identification and classification provisions in the CLP regulation, and of the inter-linkages of these provisions with risk management measures provided for in the same piece of legislation or in another piece of legislation (e.g. provisions communicating hazards to users of chemicals and setting specific legal requirements on risk management of chemicals). The same analysis should be performed for any provision identifying or categorizing hazard of chemicals that is provided for in pieces of legislation other than the CLP Regulation (e.g. the criteria for PBT/vPvB substances under the Biocidal Products and REACH Regulations, the identification of hazardous substances in the workplace under the OSH Directives).

2. Mapping out the links between the specific risk assessments and the risk management measures taken as a consequence

This will include an analysis of the specific risk assessment provisions and of the inter-linkages of these provisions with risk management measures provided for in the same piece of legislation or in another piece of legislation.

3. Examining the overall effectiveness, efficiency, relevance, coherence and EU added value of the hazard identification/generic risk considerations and specific risk assessment procedures (on their own but also compared to one another)

This will require examining the various procedures to identify hazard or specific risks provided for in EU chemicals legislation. Once the various procedures are described, their merits and shortcomings should be analysed on their own but also by comparison to one another following the FC criteria listed in section C.2 below.

4. Examining the overall effectiveness, efficiency, relevance, coherence and EU added value of the two risk management approaches adopted in the chemicals legislation, i.e. (i) risk management based on generic risk considerations and (ii) risk management based on specific risk assessment (on their own but also compared to one another)

This will require examining the two approaches to adopting risk management in EU chemicals legislation. The two approaches' merits and shortcomings should be analysed on their own but also by comparison to one another following the FC criteria listed in section C.2 below.

The FC will also address potential missing links between chemicals management legislation and identified hazard or hazard classes based on generic risk considerations, e.g. cases in

which a direct or indirect link between a risk management measure and an identified hazard via generic risk consideration may be warranted.

5. Analysing the coherence of the legislative approach and procedures regarding hazard identification, generic risk consideration, specific risk assessment or risk management measures.

This will include an analysis of the manner in which a given chemical is treated throughout the EU chemicals legislation and whether the various provisions applying to it provide for consistent definitions and coherent measures (i.e. measures adapted to the substance and the context). For instance, PBT substances are mentioned in several pieces of legislation and guidance documents, with various consequences attached to the qualification of PBT. The FC would, in this case, aim at determining whether the definition of PBT substances is identical in all pieces of legislation (or whether some differences are justified) and whether the consequences in each piece of legislation are coherent given the properties of the substance and the context of its use.

b. Legislation covered

The non-exhaustive list below contains legislation that falls within the scope of the fitness check.[1] Whilst the fitness check covers any aspects of this legislation related directly to chemicals, it does not aim to evaluate, in its entirety, each individual piece of legislation. If impacts or coherence issues of other EU legislation on the functioning of the chemicals legislation (also from the perspective of the downstream user) are noted, they may also be assessed.

The REACH Regulation is generally outside the scope of this exercise, as it has been evaluated as part of the 2012 REACH Review and will be evaluated again in 2017. Nevertheless, given the importance of hazard identification and classification criteria in this FC, Annex XIII to the REACH Regulation covering PBT and vPvB criteria will exceptionally be covered by this exercise.

1. **Legislation covering hazard identification and classification**

- Classification, labelling and packaging (Regulation No (EC) 1272/2008)
- Plant protection products (Regulation (EC) No 1107/2009)
- Biocidal products (Regulation (EU) No 528/2012)
- REACH, Annex XIII (Regulation (EC) No 1907/2006)
- Inland transport of dangerous goods (Directive 2008/68/EC)
- Chemical Agents (Directive 98/24/EC), Asbestos (Directive 2009/148/EC), Carcinogens and mutagens at work (Directive 2004/37/EC)

2. **Legislation covering risk management measures**

[1] Wherever Framework Directives are listed, the scope also includes Specific Directives (Daughter Directives) insofar as they are relevant.

a. Worker safety and transport legislation

- Inland transport of dangerous goods (Directive 2008/68/EC)
- Carcinogens and mutagens at work (Directive 2004/37/EC)
- Young people at work (Directive 1994/33/EC)
- Pregnant workers (Directive 1992/85/EEC)
- Signs at work (Directive 92/58/EEC)
- Chemical Agents (Directive 98/24/EC)
- Asbestos (Directive 2009/148/EC)

b. Environmental protection legislation

- Industrial emissions (integrated pollution prevention and control) (Directive 2010/75/EU)
- Waste framework (Directive 2008/98/EC) and List of Waste
- Waste shipments (Regulation (EC) No 1013/2006)
- Major-accident hazards involving dangerous substances (Seveso) (Directive 2012/18/EU)
- Water Framework (Directive 2000/60/EC)
- Urban Waste Water (Directive 91/271/EEC)
- Marine Strategy Framework (Directive 2008/56/EC)
- Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
- End of life vehicles (Directive 2000/53/EC)
- Batteries (Directive 2006/66/EC)
- Packaging and Packaging Waste (Directive 94/62/EC)

c. Chemicals control legislation

- Biocidal products (Regulation (EU) No 528/2012)
- Plant protection products (Regulation (EC) No 1107/2009)
- Export and import of hazardous chemicals (Regulation No 649/2012)
- Persistent organic pollutants (Regulation (EC) 850/2004)
- Contaminants in food and feed (Regulation (EEC) No 315/93 and Directive 2002/32/EC)
- Residues of pesticides (Regulation (EC) No 396/2005)

d. Product controls

- EU Ecolabel (Regulation (EC) 66/2010)
- Safety of toys (Directive 2009/48/EC)
- Cosmetic products (Regulation (EC) No 1223/2009)
- Detergents (Regulation (EC) No 648/2004)
- Drinking Water (Directive 98/83/EC)
- Fertilisers (Regulation (EC) No 2003/2003)

- Medical devices (Directive 93/42/EEC regarding medical devices, Directive 90/385/EEC regarding active implantable medical devices, and Directive 98/79/EC regarding in vitro diagnostic medical devices, under revision)15
- Aerosol dispensers (Directive 75/324/EEC)
- Explosives (Directive 93/15/EEC)
- Pressure equipment (Directive 2014/68/EU)
- Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009)
- General Product Safety (Directive 2001/95/EC)

3. Supporting legislation

- Test methods (Regulation (EC) No 440/2008)
- Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC)
- Protection of animals used for scientific purposes (Directive 2010/63/EU)

c. Issues to be examined

The FC will address the following questions related to effectiveness, efficiency, relevance, coherence, and EU added value of the legislative framework:

Effectiveness:

- To what extent does the EU legislative framework for the risk management of chemicals meet its objectives?
- What are the consequences or effects (whether socio-economic, environmental or health-related, both positive and negative) that were not originally planned (for instance, unnecessary regulatory burden, automatic mechanisms potentially triggering significant costs or benefits, obsolete measures or gaps in the legislative framework etc.)?
- What factors affect (either positively or negatively) the correct functioning of the EU legislative framework for hazard identification and risk management of chemicals? (e.g. whether the right choice is made between basing risk management measures on generic risk considerations or specific risk assessments, the combination effects of chemicals, transparency, burden of proof/duty of care, rapidity of procedures, level of evidence required and potential gaps in the legislative framework)?
- To what extent are the main elements of the EU legislative framework for the risk management effectively implemented across EU Member States (e.g. enforcement, use of the safeguard procedure)?

Efficiency:

- What are the costs and benefits associated with the implementation of the legislative framework for chemicals? To what extent are the costs proportionate to the benefits? What are the key drivers for those costs and benefits? A specific focus will be given to SMEs.

- What aspects of the functioning of the framework (including procedural aspects such as the development of scientific opinions, work of scientific committees, urgency procedures, etc.) are the most efficient and what are the least efficient?

Coherence:

- To what extent are the legal acts consistent in how they attempt to reach the stated objectives and can differences in the hazard identification and risk management of chemicals be justified?
- What, if any, are the inconsistencies, contradictions, unnecessary duplication, overlap or missing links between different pieces of legislation? Are these leading to unintended results?

Relevance:

- To what extent do the objectives of the legislative framework for chemicals meet the current needs? (e.g. through adaptations to technical and scientific progress)
- To what extent does the current legislative framework for chemicals take into account health, environmental, social and economic consequences that are relevant to citizens and stakeholders (e.g. through stakeholder information, consultation or involvement)?
- To what extent are the current procedures transparent and robust enough to enable decisions related to hazard identification, risk assessment and risk management to be relevant and evidence-based?

EU added value

- What is the added value of regulating the risk management of chemicals at an EU rather than at national level?